



Leslie Morioka
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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,738,974

MAR 14 2007

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,738,974, which claims the human drug product NEXIUM® (esomeprazole magnesium), methods of use thereof and a pharmaceutical composition comprising NEXIUM® (esomeprazole magnesium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 865 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 865 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 28, 2002, (67 Fed. Reg. 9299). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} \text{ (Testing Phase) + Approval Phase} \\ &= \frac{1}{2} (838) + 446 \\ &= 865 \text{ days (2.4 years)}\end{aligned}$$

Since the regulatory review period began, after the patent issued (April 19, 1988), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

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|---|---------------------|
| U.S. Patent No.: | 4,738,974 |
| Granted: | April 19, 1988 |
| Original Expiration Date ¹ : | April 19, 2005 |
| Applicant: | Arne E. Brändström |
| Owner of Record: | Aktiebologet Hassle |


¹Subject to the provisions of 35 U.S.C. § 41(b).

Title: Base Addition Salts of Omeprazole
Product Trade Name: NEXIUM® (esomeprazole magnesium)
Term Extended: 865 days
Expiration Date of Extension: September 1, 2007

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.


Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

RE: NEXIUM® (esomeprazole magnesium)
FDA Docket No.: 01E-0365

Attention: Beverly Friedman